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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
12/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,137	BERINSTEIN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2009 and 05 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67,69 and 73-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67,69 and 73-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of the invention of Group II and the species LMDMQTFKA (SEQ ID NO:7) in the reply filed on January 7, 2009 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

2. The response filed November 5, 2009 included a clean copy of the seven pages of the specification which were amended by the specification amendment filed on the same date. These pages have not been entered, and should not have been submitted, because there is no longer any provision in the rules for submission of clean copies of amendments. The clean copy of the specification amendments does not comply either with 37 CFR 1.121(b) or with 37 CFR 1.125.

The amendment to the specification filed November 5, 2009 has not been entered because the proposed amendment to page 34, line 26, does not comply with 37 CFR 1.121(b)(1)(ii), i.e. does not include the full text of the replacement paragraph.

If the amendment to the specification had been submitted in appropriate form under 37 CFR 1.121(b), the amendment would have been entered and would have overcome the objection to the drawings and the objection to the specification repeated in sections 4 and 5 below.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

SEQ ID NO:51 as set forth in Table IV, and now recited in claims 67 and 75, does not correspond with SEQ ID NO:51 as defined in the Sequence Listing filed June 28, 2007 (computer readable form copy) and November 5, 2009 (paper copy).

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

4. The drawings are objected to because SEQ ID NOS need to be inserted after the amino acid and nucleotide sequences recited in the drawings. See 37 CFR 1.821(d). In the alternative, and more preferably, SEQ ID NOS can be inserted into the Brief Description of these drawings occurring at page 2 of the specification. If necessary, corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The disclosure is objected to because of the following informalities: SEQ ID NOS must be inserted after all amino acid and nucleotide sequences disclosed in the specification which are

subject to the sequence disclosure rules. See 37 CFR 1.821(d). Such sequences occur at, e.g., pages 14 and 30-34 of the specification. Appropriate correction is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New claims 76-78 recite a method for inducing an immune response in a host, without any recitation of the type of immune response which is to be induced. The original disclosure is limited to inducing an immune response in order to treat or prevent cancer (see, e.g., page 1, lines 30-31, and page 2, lines 2-3 and 19-20 of the specification) and inducing an immune response against the tumor antigen BFA5 (see, e.g., originally filed claim 37). The new claims are broader in scope than the original disclosure, and therefore lack support in the written description of the invention. Applicants have not indicated where the new claim language is supported by the original disclosure of the invention.

7. Claims 67, 69, and 73-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 67, 73, and 75, it is not clear if the claim language should be interpreted as defining the peptides using open or closed language, i.e. it is not clear if the claims embrace peptides comprising the recited amino acid sequences plus additional amino

acids and/or modifying groups. The word "having" as is used in claim 73 has no settled meaning in the art. Claims 67 and 75 are indefinite because SEQ ID NO:51 as set forth in Table IV, and now recited in claims 67 and 75, does not correspond with SEQ ID NO:51 as defined in the Sequence Listing filed June 28, 2007 (computer readable form copy) and November 5, 2009 (paper copy).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 67, 69, and 73-78 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 01/47959. The WO Patent Application '959 teaches the peptides ELMDMQTFKA and SLSKILDTV, which can be included as part of an immunogenic cocktail composition. See, e.g., page 25, lines 13-15; the paragraph bridging pages 26 and 27; and the paragraph bridging pages 28 and 29. The peptide ELMDMQTFKA is the same as Applicants' SEQ ID NO:7, except with an additional N-terminal glutamic acid residue. Note that it is unclear as to whether Applicants' claims exclude the presence of any additional amino acid residues from their claimed peptides. See the above rejection under 35 U.S.C. 112, second paragraph. The peptide SLSKILDTV is the same as that listed in Applicants' Table IV, column 1, eighth entry (SEQ ID NO:28). In view of the similarity in amino acid sequence and utility

between the ELMDMQTFKA of the WO Patent Application '959 and Applicants' elected peptide, inherently the ELMDMQTFKA of the WO Patent Application '959 will be immunogenic as determined by ELISPOT analysis of human T-cell cultures or human T cell cytotoxicity assay to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the WO Patent Application '959 and Applicants' claimed invention to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than the WO Patent Application '959.

10. Claims 67, 69, and 73-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Jager et al (U.S. Patent No. 6,911,529). Jager et al teach an isolated cancer associated antigen having the amino acid sequence identified as SEQ ID NO:16. The antigen can be combined with a pharmaceutically acceptable adjuvant and used as an immunogenic composition. See, e.g., column 12, lines 37-43; column 13, lines 17-37; and claims 1, 6, 7, 10, and 12. Jager et al's SEQ ID NO:16 comprises Applicants' SEQ ID NO:7 at residues 12-20 and Applicants' SEQ ID NO:38 at residues 430-438. Note that it is unclear as to whether Applicants' claims exclude the presence of any additional amino acid residues from their claimed peptides. See the above rejection under 35 U.S.C. 112, second paragraph. In view of the similarity in amino acid sequence and utility between Jager et al's cancer associated antigen identified as SEQ ID NO:16 and Applicants' elected peptide, inherently Jager et al's cancer associated antigen will be immunogenic as determined by ELISPOT analysis of human T-cell cultures or human T cell cytotoxicity assay to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between Jager et al and Applicants' claimed invention to shift the burden to

Applicants to provide evidence that the claimed invention is unobviously different than Jager et al.

11. Applicant's arguments filed August 3, 2009 and November 5, 2009 have been fully considered but they are not persuasive.

The rejection under 35 U.S.C. 112, second paragraph, concerning whether the peptides are defined using open or closed language is maintained. Applicants did not directly answer the issue raised by the rejection, but noted that the claims now refer to specific SEQ ID NOS. However, the SEQ ID NOS as defined in the Sequence Listing do not specify whether the claim language should be interpreted as open or closed language. Note that a sequence length specified in a Sequence Listing is not an indication of open or closed language. For example, "a peptide comprising LMDMQTFKA" and "a peptide consisting of LMDMQTFKA" would both be given a sequence length <211> of 9 in a sequence listing.

The anticipation rejection under 35 U.S.C. 102(b) based upon the WO Patent Application 01/47959 is maintained. As noted above, Applicants have not directly answered whether the peptides recited in the pending claims are defined using open or claimed terminology. In the absence of any clear indication to the contrary, the claims will be given their broadest reasonable interpretation consistent with the specification, i.e. will be interpreted as defining the peptides using open-ended or the equivalent of "comprising" terminology. This interpretation is considered to be consistent with the specification, which discloses and exemplifies modified peptide sequences, i.e. peptides having Applicants' SEQ ID NOS to which additional amino acids have been added. See, e.g., page 14, lines 14-28; page 16, lines 8-12; and page 34, lines 5-10. Applicants assert that their claims do not encompass a peptide having the amino acid

sequence ELMDMQTFKA, but have not pointed to any claim terminology which would support this assertion.

Applicants' remarks directed towards proceeding contrary to accepted wisdom being evidence of nonobviousness are noted; however, this analysis is relevant only towards obviousness rejections. The WO Patent Application '959 and Jager et al are applied under 35 U.S.C. 102 on the basis of anticipation.

In the rejection based upon the WO Patent Application '959, the examiner has corrected a misspelling of the peptide sequence ELMDMQTFKA which was present in the rejection contained in the previous Office action. The examiner apologizes for any confusion this error might have caused Applicants.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
December 14, 2009